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UNITED STATES DISTRICT COURT
 SOUTHERN DISTRICT OF NEW YORK

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IN RE:	:	
Fosamax Products Liability Litigation	:	1:06-md-1789 (JFK)
	:	
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<i>This Document Relates to:</i>	:	ANSWER AND AFFIRMATIVE
Vivian Zale and	:	DEFENSES OF MERCK
Robert Zale	:	& CO., INC.;
v. Merck & Co., Inc.	:	DEMAND FOR JURY TRIAL
	:	
Case No: 1:08-cv-5377-JFK	:	
	:	
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Defendant, Merck & Co., Inc. (“Merck”), by and through its undersigned attorneys, hereby answers the Complaint. Merck denies all allegations set forth in the Complaint except to the extent such allegations are specifically admitted below:

PARTIES

1. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 1.
2. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 2.
3. Merck admits that it is a corporation organized under the laws of the State of New Jersey with its principal place of business located at One Merck Drive,

Whitehouse Station, New Jersey. Except as expressly admitted herein, Merck denies the remaining allegations of Paragraph 3.

4. Merck admits that it is registered to do business in the State of Florida.

5. Merck is without knowledge as to what is meant by the phrase “regularly transacted,” so the remaining allegations in Paragraph 5 are denied.

6. Merck denies each and every allegation of Paragraph 6, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 6 inconsistent with that prescribing information and respectfully refers the Court to the Physicians’ Desk Reference (“PDR”) for FOSAMAX® for its actual language and full text.

7. Merck admits only that it distributed FOSAMAX® for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 7 inconsistent with that prescribing information. Merck respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text. Except as expressly admitted herein, Merck denies the remaining allegations of Paragraph 7.

8. Merck is without knowledge as to what is meant by the phrase “substantial revenue,” so the allegations in Paragraph 8 are denied.

9. Merck is without knowledge as to what is meant by “consequences,” so the allegations in Paragraph 9 are denied.

JURISDICTION AND VENUE

10. Merck is without knowledge as to the allegations of Paragraph 10, but for jurisdictional purposes only, admits that the Plaintiffs seek in excess of \$75,000.

11. The allegations of Paragraph 11 are conclusions of law to which no response is required. To the extent that a response is required, Merck denies each and every allegation of Paragraph 11.

12. The allegations of Paragraph 12 are conclusions of law to which no response is required. To the extent that a response is required, Merck denies each and every allegation of Paragraph 12.

FACTUAL BACKGROUND

13. Merck denies each and every allegation of Paragraph 13, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

14. Merck denies each and every allegation of Paragraph 14, except that Merck admits that it sought and, in 1995, first obtained FDA approval to manufacture and market FOSAMAX® 10 mg and FOSAMAX® 40 mg tablets, a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 14 inconsistent with that prescribing information and respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text.

15. Merck admits only that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 15 inconsistent with that prescribing information. Merck respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text. Merck also refers the Court to the prescribing information

for Aredia and Zometa, and denies any allegations in Paragraph 15 with respect to Aredia and Zometa inconsistent with that prescribing information.

16. Merck admits only that some bisphosphonates contain nitrogen and some do not and that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text. Merck also refers the Court to the prescribing information for Aredia, Bondronat, Didronel, Bonefos, Loron, and Skelid, and denies any allegations in Paragraph 16 with respect to Aredia, Bondronat, Didronel, Bonefos, Loron, and Skelid inconsistent with that prescribing information. Merck denies the remaining allegations of Paragraph 16.

17. Merck denies each and every allegation of Paragraph 17.

18. Merck denies each and every allegation of Paragraph 18.

19. Merck denies each and every allegation of Paragraph 19.

20. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 20.

21. Merck denies each and every allegation of Paragraph 21.

22. Merck denies each and every allegation of Paragraph 22.

23. Merck denies each and every allegation of Paragraph 23.

24. Merck denies each and every allegation of Paragraph 24.

25. Merck denies each and every allegation of Paragraph 25, except that Merck admits that the FDA drafted an “ODS Postmarketing Safety Review,” but respectfully refers the Court to said document for its actual language and full text.

26. Merck denies each and every allegation of Paragraph 26.

27. Merck denies each and every allegation of Paragraph 27.

28. Merck denies each and every allegation of Paragraph 28.

29. Merck denies each and every allegation of Paragraph 29, except that Merck admits that Fosamax product sales in 2007 amounted to approximately \$3.05 billion.

30. Merck is without knowledge as to whether Plaintiff used FOSAMAX®. Merck denies the remaining allegations in Paragraph 30.

31. Merck denies each and every allegation of Paragraph 31.

32. Merck is without knowledge as to whether Plaintiff was prescribed FOSAMAX®. Merck denies the remaining allegations in Paragraph 32.

33. Merck denies each and every allegation of Paragraph 33.

34. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 34.

35. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 35.

36. Merck denies each and every allegation of Paragraph 36.

37. Merck denies each and every allegation of Paragraph 37.

38. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 38.

39. Merck denies each and every allegation of Paragraph 39.

40. Merck denies each and every allegation of Paragraph 40.

41. Merck denies each and every allegation of Paragraph 41.

COUNT I

STRICT LIABILITY

42. Merck repleads its answers to Paragraphs 1 through and including 41, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

43. Merck denies each and every allegation of Paragraph 43, except that it admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

44. Merck denies each and every allegation of Paragraph 44, except that it admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information and states that it is without knowledge as to the condition of the FOSAMAX® Plaintiff alleges she consumed.

45. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 45.

46. Merck denies each and every allegation of Paragraph 46.

47. Merck denies each and every allegation of Paragraph 47.

48. Merck denies each and every allegation of Paragraph 48.

49. Merck denies each and every allegation of Paragraph 49.

50. Merck denies each and every allegation of Paragraph 50.

51. Merck denies each and every allegation of Paragraph 51.

52. Merck denies each and every allegation of Paragraph 52.

53. Merck denies each and every allegation of Paragraph 53.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs' Complaint with prejudice and awarding Merck its reasonable attorney's fees, together with such other and further relief that the Court may deem just and proper.

COUNT II
NEGLIGENCE

54. Merck repleads its answers to Paragraphs 1 through and including 53, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

55. The allegations in Paragraph 55 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, Merck respectfully refers the Court to the relevant legal standard, including any conflict of law rules.

56. Merck denies each and every allegation of Paragraph 56, including each and every allegation contained in subparts (a) through (f).

57. Merck denies each and every allegation of Paragraph 57.

58. Merck denies each and every allegation of Paragraph 58.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs' Complaint with prejudice and awarding Merck its reasonable attorney's fees, together with such other and further relief that the Court may deem just and proper.

COUNT III

NEGLIGENT MISREPRESENTATION

59. Merck repleads its answers to Paragraphs 1 through and including 58, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

60. Merck denies each and every allegation of Paragraph 60, including each and every allegation contained in subparts (a) and (b).

61. Merck denies each and every allegation of Paragraph 61.

62. Merck denies each and every allegation of Paragraph 62.

63. Merck denies each and every allegation of Paragraph 63.

64. Merck denies each and every allegation of Paragraph 64.

65. Merck denies each and every allegation of Paragraph 65.

66. Merck denies each and every allegation of Paragraph 66.

67. Merck denies each and every allegation of Paragraph 67.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs' Complaint with prejudice and awarding Merck its reasonable attorney's fees, together with such other and further relief that the Court may deem just and proper.

COUNT IV

FRAUDULENT CONCEALMENT

68. Merck repleads its answers to Paragraphs 1 through and including 67, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

69. Merck denies each and every allegation of Paragraph 69, including each and every allegation contained in subparts (a) and (b).

70. Merck denies each and every allegation of Paragraph 70.

71. Merck denies each and every allegation of Paragraph 71.

72. Merck denies each and every allegation of Paragraph 72.

73. Merck denies each and every allegation of Paragraph 73.

74. Merck denies each and every allegation of Paragraph 74.

75. Merck denies each and every allegation of Paragraph 75.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs' Complaint with prejudice and awarding Merck its reasonable attorney's fees, together with such other and further relief that the Court may deem just and proper.

COUNT V

BREACH OF IMPLIED WARRANTY

76. Merck repleads its answers to Paragraphs 1 through and including 75, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

77. Merck denies each and every allegation of Paragraph 77, except that Merck admits that it manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

78. Merck denies each and every allegation of Paragraph 78, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a

prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

79. Merck denies each and every allegation of Paragraph 79.

80. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 80.

81. Merck denies each and every allegation of Paragraph 81.

82. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 82.

83. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 83.

84. Merck denies each and every allegation of Paragraph 84.

85. Merck denies each and every allegation of Paragraph 85.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs' Complaint with prejudice and awarding Merck its reasonable attorney's fees, together with such other and further relief that the Court may deem just and proper.

COUNT VI

BREACH OF EXPRESS WARRANTY

86. Merck repleads its answers to Paragraphs 1 through and including 85, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

87. Merck denies each and every allegation of Paragraph 87, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a

prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

88. Merck denies each and every allegation of Paragraph 88.

89. Merck denies each and every allegation of Paragraph 89.

90. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 90.

91. Merck denies each and every allegation of Paragraph 91.

92. Merck denies each and every allegation of Paragraph 92.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs' Complaint with prejudice and awarding Merck its reasonable attorney's fees, together with such other and further relief that the Court may deem just and proper.

COUNT VII

LOSS OF CONSORTIUM

93. Merck repleads its answers to Paragraphs 1 through and including 92, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

94. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 94.

95. Merck denies each and every allegation of Paragraph 95.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs' Complaint with prejudice and awarding Merck its reasonable attorney's fees, together with such other and further relief that the Court may deem just and proper.

COUNT VIII

INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

96. Merck repleads its answers to Paragraphs 1 through and including 95, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

97. Merck denies each and every allegation of Paragraph 97.

98. Merck denies each and every allegation of Paragraph 98.

99. Merck denies each and every allegation of Paragraph 99.

100. Merck denies each and every allegation of Paragraph 100.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs' Complaint with prejudice and awarding Merck its reasonable attorney's fees, together with such other and further relief that the Court may deem just and proper.

COUNT IV

NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

101. Merck repleads its answers to Paragraphs 1 through and including 100, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

102. Merck denies each and every allegation of Paragraph 102, including each and every allegation contained in subparts (a) through (d).

103. Merck denies each and every allegation of Paragraph 103.

104. Merck denies each and every allegation of Paragraph 104.

105. Merck denies each and every allegation of Paragraph 105.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs' Complaint with prejudice and awarding Merck its reasonable attorney's fees, together with such other and further relief that the Court may deem just and proper.

AFFIRMATIVE DEFENSES

Discovery and investigation may reveal that any one or more of the following affirmative defenses should be available to Merck in this matter. Merck, therefore, asserts said affirmative defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Merck may withdraw any of these affirmative defenses as may be appropriate. Further, Merck reserves the right to amend its Answer to assert additional defenses, cross-claims, counterclaims, and other claims and defenses as discovery proceeds. Further answering and by way of additional defense, Merck states as follows:

FIRST AFFIRMATIVE DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations and is otherwise untimely.

SECOND AFFIRMATIVE DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

THIRD AFFIRMATIVE DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

FOURTH AFFIRMATIVE DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening cause or causes.

FIFTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs assert claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

SIXTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs assert claims based upon an alleged failure by Merck to warn Plaintiffs directly of alleged dangers associated with the use of FOSAMAX®, such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to the prescribing physician.

SEVENTH AFFIRMATIVE DEFENSE

Other persons or entities who are not parties to this suit were guilty of negligence which was the sole proximate cause of, or a contributing cause to, the damages alleged in the Complaint. Merck anticipates more specific information regarding the identity and potential liability of these non-parties will be developed during discovery. Accordingly, any damages awarded should be apportioned.

EIGHTH AFFIRMATIVE DEFENSE

The injuries and damages, if any, sustained by the Plaintiffs resulted in whole or in part from their own comparative negligence and any damages recovered should be reduced accordingly.

NINTH AFFIRMATIVE DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or losses were only sustained after Plaintiff knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any medicine or pharmaceutical preparation manufactured or distributed by Merck or another manufacturer.

TENTH AFFIRMATIVE DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

ELEVENTH AFFIRMATIVE DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiff's misuse or abuse of FOSAMAX®.

TWELFTH AFFIRMATIVE DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiffs' pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, idiosyncratic reactions, subsequent medical conditions or natural courses of conditions for which this Defendant is not responsible.

THIRTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims for breach of warranty are also barred for lack of timely notice of breach and/or lack of privity.

FOURTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part under the applicable state law because FOSAMAX® was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

SIXTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused the injuries asserted in the Complaint, such an award would, if granted, violate Merck's state and federal constitutional rights.

SEVENTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs seek punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

EIGHTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs seek punitive damages, such claim is barred because FOSAMAX® and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

NINETEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

TWENTIETH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part because Merck provided legally adequate "directions or warnings" as to the use of FOSAMAX® and any other medicine or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

TWENTY-FIRST AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred under Section 4, *et seq.*, of the Restatement (Third) of Torts: Products Liability.

TWENTY-SECOND AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred under comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

TWENTY-THIRD AFFIRMATIVE DEFENSE

There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of FOSAMAX®.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part by failure to mitigate damages.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part because Merck's conduct conforms with medical knowledge.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

With respect to each and every cause of action, Plaintiffs are not entitled to recovery for strict liability because Plaintiffs cannot state claims founded in strict liability because, among other things, comments j and k to Section 402A of the Restatement (Second) of Torts relegates Plaintiffs' claims to a negligence cause of action.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

All activities of Merck as alleged in the Complaint were expressly authorized and/or regulated by a government agency. Therefore, Plaintiffs' claims pertaining to unfair or deceptive practices are barred.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

With respect to each and every cause of action, Plaintiffs are not entitled to recover because if the product involved was unsafe, which Merck denies, then it was unavoidably unsafe as defined in Restatement of Torts. The apparent benefits of the product exceeded any apparent risk given the scientific knowledge available when the product was marketed.

TWENTY-NINTH AFFIRMATIVE DEFENSE

Merck's advertisements and labeling with respect to the products which are the subject matter of this action were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States, Florida, and New York Constitutions.

THIRTIETH AFFIRMATIVE DEFENSE

The public interest in the benefit and availability of the product which is the subject matter of this action precludes liability for risks, if any, resulting from any

activities undertaken by Defendant, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiffs' claims, if it is determined there is a risk inherent in the product which is the subject matter of this action, then such risk, if any, is outweighed by the benefit of the product.

THIRTY-FIRST AFFIRMATIVE DEFENSE

At all times relevant herein, any product which is the subject matter of this action processed and distributed by Merck in any state in the United States was processed and distributed in a reasonable and prudent manner based upon available medical and scientific knowledge and further was processed and distributed in accordance with and pursuant to all applicable regulations of the FDA.

THIRTY-SECOND AFFIRMATIVE DEFENSE

With respect to each and every purported cause of action, the acts of Merck were at all times done in good faith and without malice.

THIRTY-THIRD AFFIRMATIVE DEFENSE

To the extent there were any risks associated with the use of the product which is the subject matter of this action which Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and state law.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiffs have not sustained an ascertainable loss of property or money.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiffs have not suffered any actual injury or damages.

THIRTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred under the doctrine of economic loss.

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

This case is more appropriately brought in a different venue as defined in 28 U.S.C. §1404(a).

THIRTY-EIGHTH AFFIRMATIVE DEFENSE

This case is subject to dismissal and/or transfer to another venue pursuant to 28 U.S.C. §1406(a).

THIRTY-NINTH AFFIRMATIVE DEFENSE

This case is subject to dismissal or stay on the grounds of *forum non conveniens*.

FORTIETH AFFIRMATIVE DEFENSE

Plaintiffs' claims of fraud are not pleaded with the required particularity.

FORTY-FIRST AFFIRMATIVE DEFENSE

Plaintiffs cannot recover for the claims asserted because Plaintiffs have failed to comply with the conditions precedent necessary to bring this action and/or each particular cause of action asserted by Plaintiffs.

FORTY-SECOND AFFIRMATIVE DEFENSE

Plaintiffs' claims for breach of warranty are barred because Plaintiffs did not rely on such warranties and the claims are otherwise barred for lack of timely notice, lack of privity and/or because the alleged warranties were disclaimed.

FORTY-THIRD AFFIRMATIVE DEFENSE

An asymptomatic plaintiff lacks standing because she has suffered no damages and no injury-in-fact.

FORTY-FOURTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs assert claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products, FDA Docket No. 2000N-1269 (January 24, 2006).

FORTY-FIFTH AFFIRMATIVE DEFENSE

The substantive law of Florida applies to Plaintiffs' claims.

In so much as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Merck to determine all of its legal, contractual and equitable rights, Merck reserves the right to amend and/or supplement the averments of its Answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery.

Merck will rely on all defenses that may become available during discovery or trial.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs' Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

JURY DEMAND

Merck demands a trial by jury as to all issues so triable.

DATED: New York, New York
July 15, 2008

Respectfully submitted,

HUGHES HUBBARD & REED LLP

By: _____/s/_____
Norman C. Kleinberg
Theodore V. H. Mayer
William J. Beausoleil

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Attorneys for Defendant Merck & Co., Inc.

CERTIFICATE OF SERVICE

I hereby certify that on this 15th day of July, 2008, I caused a copy of the foregoing ANSWER AND AFFIRMATIVE DEFENSES OF MERCK & CO., INC. to be served via first-class mail, postage prepaid, on the following:

MORGAN & MORGAN, P.A.
Michael Goetz, Esquire
301 North Franklin Street, 7th Floor
Tampa, Florida 33602

The above address has appeared on the prior papers in this action as the office address of the attorneys for Plaintiffs.

Deponent is over the age of 18 years and not a party to this action.

I further certify under penalty of perjury that under the laws of the United States of America the foregoing is true and correct.

Executed on July 15, 2008

/s/
Shawn McEnnis